Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (currently amended) A polymeric composition having improved capability to solubilize a drug in a hydrophilic environment, comprising: a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons,

wherein the polymeric composition has a block copolymer concentration in the range of about 5 to 40%, and said polymeric composition when formed as an aqueous polymer solution, remains a free flowing liquid upon parenteral administration to a warm blooded animal and at temperatures between 35 and 42°C.

2. (previously presented) The polymeric composition according to claim 1 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

3. (original) The polymeric composition according to claim 1 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

4. (currently amended) A biodegradable polymeric drug delivery composition capable of solubilizing a drug in a hydrophilic environment to form a solution, comprising:

(a) an effective amount of a drug; and

(b) a biodegradable ABA-type, or BAB-type block copolymer comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons,

wherein the polymeric composition has a block copolymer concentration in the range of about 5 to 40%, and said composition remains a free flowing liquid upon parenteral administration to a warm blooded animal and at temperatures between 35 and 42°C.

5. (previously presented) The polymeric drug delivery composition according to claim 4 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

6. (original) The polymeric drug delivery composition according to claim 4 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

7. (original) The polymeric drug delivery composition according to claim 4 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

8. (currently amended) A biodegradable polymer solution as a drug delivery vehicle capable of solubilizing a drug in a hydrophilic environment, comprising: a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer and an aqueous solution, said block copolymer comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons;

and wherein the polymeric composition has a block copolymer concentration in the range of about 5 to 40%, and said polymer solution remains a free flowing liquid upon parenteral administration to a warm blooded animal and at temperatures between 35 and 42°C.

9. (previously amended) The polymeric solution according to claim 8, wherein said block copolymer concentration is between about 10 to 30% by weight of said polymer solution.

10. (previously presented) The polymeric composition according to claim 8 wherein the

biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

11. (original) The polymeric composition according to claim 8 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

12. (currently amended) A biodegradable drug solution comprising:

(a) an effective amount of a drug solubilized in a polymer solution comprising;

(1) a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer capable of solubilizing said drug in a hydrophilic environment, comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the tri-block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons; and

(2) an aqueous solution, wherein the polymeric composition has a block copolymer concentration in the range of about 5 to 40%, and said polymer solution remains a free flowing liquid upon parenteral administration to a warm blooded animal and at temperatures between 35 and 42°C.

13. (original) The biodegradable aqueous polymeric drug solution according to claim 12 further comprising excipients, additives, buffers, osmotic pressure adjusting agents, antioxidants, preservatives, drug stabilizing agents or equivalents thereof.

14. (previously amended) The biodegradable aqueous polymeric drug solution according to claim 12, wherein said block copolymer concentration is between about 10 to 30% by weight of said polymer solution.

15. (original) The biodegradable aqueous polymeric drug solution according to claim 12 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

16. (previously presented) The biodegradable aqueous polymeric drug solution according to claim 12 wherein the biodegradable polyester of the hydrophobic A polymer block is

synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

17. (original) The biodegradable aqueous polymeric drug solution according to claim 12 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

18. (currently amended) A method for administering a drug to a warm blooded animal, comprising

(1) providing a biodegradable polymeric drug delivery composition comprising:

(a) an effective amount of a drug; and

(b) a biodegradable ABA-type, or BAB-type block copolymer comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons,

wherein the polymeric composition has a block copolymer concentration in the range of about 5 to 40%, and said polymeric composition remains a free flowing liquid upon parenteral administration to said warm blooded animal and at temperatures between 35 and 42°C, and

(2) administering said composition to said warm blooded animal.

19. (previously presented) The method according to claim 18 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

20. (original) The method according to claim 18 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

21. (original) The method according to claim 18 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

22. (original) The method according to claim 18 wherein said administration is by parenteral, ocular, topical, inhalation, transdermal, vaginal, buccal, transmucosal, transurethral, rectal, nasal, oral, peroral, pulmonary or aural means.

23. (currently amended) A method for administering a drug to a warm blooded animal, comprising

(1) providing a biodegradable polymeric drug solution comprising an effective amount of a drug solubilized in a polymer solution comprising;

(a) a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer capable of solubilizing said drug in a hydrophilic environment, comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol(PEG), and wherein the tri-block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons; and

(b) an aqueous solution, wherein the polymeric solution has a block copolymer concentration in the range of about 5 to 40%, and said polymer solution remains a free flowing liquid upon parenteral administration to said warm blooded animal and at temperatures between 35 and 42°C, and;

(2) administering said drug solution to said warm blooded animal.

24. (previously amended) The method according to claim 23, wherein the block copolymer concentration is between about 10 to 30% by weight of said polymer solution.

25. (previously presented) The method according to claim 23 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

26. (original) The method according to claim 23 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

27. (original) The method according to claim 23 wherein the drug content is 10^{-6} to 100% of

the total triblock copolymer weight.

28. (original) The method according to claim 23 wherein said administration is by intramuscular, intraperitoneal, intra-abdominal, subcutaneous, intrathecal, intrapleural, intravenous or intraarterial means.

29. (currently amended) A method for enhancing the solubility of a drug, comprising
1) preparing a polymeric composition comprising a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons,

2) admixing the polymeric composition with a drug; and
3) admixing the drug containing polymeric composition with an aqueous solution to obtain a drug solution that has a block copolymer concentration in the range of about 5 to 40%, and that remains a free flowing liquid upon parenteral administration to a warm blooded animal and at temperatures between 35 and 42°C.

30. (previously amended) The method according to claim 23, wherein the block copolymer concentration is between about 10 to 30% by weight of said polymer solution.

31. (previously presented) The method according to claim 29 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

32. (original) The method according to claim 31 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

33. (original) The method according to claim 29 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

34. (currently amended) A method for enhancing the solubility of a drug, comprising
1) preparing a polymeric composition comprising a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons,

2) admixing said composition with an aqueous solution to form a polymeric solution that has a block copolymer concentration in the range of about 5 to 40%, and that remains a free flowing liquid upon parenteral administration to a warm blooded animal and at temperatures between 35 and 42°C, and

3) admixing said polymer solution with a drug to form a drug solution.

35. (previously amended) The method according to claim 34, wherein the block copolymer concentration is between about 10 to 30% by weight of said polymer solution.

36. (previously presented) The method according to claim 34 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

37. (original) The method according to claim 34 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

38. (original) The method according to claim 34 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

39. (currently amended) A method for enhancing the solubility of a drug, comprising
1) preparing a polymeric composition comprising a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene

glycol (PEG), and wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons,

2) admixing a drug with an aqueous solution to form a drug-aqueous solution mixture, and

3) admixing said polymer composition with said drug-aqueous solution mixture to form a drug polymeric solution that has a block copolymer concentration in the range of about 5 to 40%, and that remains a free flowing liquid upon parenteral administration to a warm blooded animal and at temperatures between 35 and 42°C.

40. (previously amended) The method according to claim 39, wherein the block copolymer concentration is between about 10 to 30% by weight of said polymer solution.

41. (previously presented) The method according to claim 39 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers including D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, or copolymers thereof.

42. (previously presented) The method according to claim 39 wherein the A-block comprises of between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

43. (previously presented) The method according to claim 39 wherein the drug content is 10^{-6} to 100% of the total tri block copolymer weight.

44. (cancelled)

45. (cancelled)

46. (cancelled)

47. (cancelled)